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10/650,253	08/27/2003	Zheng J. Li	PC11724D	7178

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PATENT DEPARTMENT, MS8260-1611
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EXAMINER	
PESELEV, ELLI	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/650,253
Filing Date: August 27, 2003
Appellant(s): LI ET AL.

Lance Y. Liu
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 3, 2006 appealing from the Office action mailed March 16, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Interference No. 105,366 (McK) between Junior party (applications 10/652,655 and 10/650,252) and senior party (U.S. Patent No. 6,365,574 and application 10/816,376) is pending.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,474,768	BRIGHT	10-1984
5,605,889	CURATOLO et al	2-1997
6,365,574	SINGER et al	4-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 125 and 128-144 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The present claims are directed to a pharmaceutical dosage form comprising a crystalline azithromycin hemi-ethanol solvate and a pharmaceutically acceptable carrier or diluent. On page 32 of the specification, lines 32-33, it is stated that carriers include sterile aqueous media. Therefore, the claimed dosage form encompasses a crystalline compound in an aqueous media. Since a crystalline compound cannot maintain its crystalline structure in an aqueous media, the claimed dosage form of a crystalline compound are not enabled.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 125 and 128-144 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bright (U.S. Patent No. 4,474,768).

Bright discloses azithromycin in dosage form (column 7, lines 22-30). The present claims are directed to a pharmaceutical dosage form comprising substantially pure monohydrate hemi-ethanol solvate and a pharmaceutically acceptable carrier or diluent. Note that a pharmaceutically acceptable carrier or diluent encompasses aqueous media and that a crystalline azithromycin monohydrate hemi-ethanol solvate

cannot maintain its crystalline structure in aqueous media. Therefore, the claimed dosage form encompasses nothing more than a dosage form comprising the same n or substantially the same as disclosed by Bright.

Claims 125 and 128-144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singer et al (U.S. Patent No. 6,365,574) in view of Curatolo et al (U.S. Patent No. 5,605,889).

Singer et al disclose a pharmaceutical composition comprising crystalline hemi-ethanol (columns 3-4) but do not disclose said composition in dosage form. However, since a pharmaceutical dosage form of azithromycin was well known in the art at the time the present invention was made as disclosed by Curatolo et al (column 2, lines 35-45), a person having ordinary skill in the art at the time the present invention was made would have been motivated to prepare the composition disclosed by Singer et al in dosage form.

(10) Response to Argument

With respect to the rejection of claims 125 and 128-144 under 35 U.S.C. 112, first paragraph, Appellant contends that the claimed pharmaceutical dosage would not cover dosage forms where substantially pure crystalline azithromycin monohydrate hemi-ethanol solvate cannot be detected and/or characterized. This argument has not been found persuasive since the present claims are directed to a dosage form of a crystalline compound. A dosage form of a compound implies a certain level of concentration of said compound. Appellant has not presented any arguments or evidence how a crystalline compound can maintain its

crystalline structure in aqueous media. Further, even if some crystalline form of a compound could be detected, as argued by appellant, the claimed dosage form would not be enabled as to its dosage amount.

Appellant's argument with respect to the Rouhi reference is not persuasive insofar as the claimed dosage form encompasses an aqueous carrier since a crystalline compound cannot maintain its crystalline structure once it's dissolved in an aqueous carrier.

With respect to the rejection of claims 125 and 128-144 as being anticipated by Bright, appellant contends that the declaration by Dr. Hangac confirmed that Bright produced azithromycin form B and not substantially pure azithromycin ethanolate. This argument has not been found persuasive since the present claims encompass substantially pure azithromycin ethanolate in an aqueous carrier. Appellant has not shown how crystalline azithromycin ethanolate encompassed by the present claims, one dissolved in an aqueous carrier, is different from azithromycin disclosed by Bright.

With respect to the rejection of claims 125 and 128-144 under 35 U.S.C. 103(a) as being obvious over Bright, appellant contends that the present claims do not cover an aqueous solution of azithromycin monohydrate hemi-ethanol solvate. This argument has not been found persuasive since the specification on page 32, lines 32-33 defines a carrier as including an aqueous media. Note that Bright discloses a dosage form of an azithromycin compound (column 7, lines 50-53). Once dissolved in an aqueous media, the claimed crystalline azithromycin

monohydrate hemi-ethanol solvate would be the same or substantially the same as the azithromycin compound disclosed by Bright.

With respect to the rejection of 125 and 128-144 under 35 U.S.C. 103(a) as being unpatentable over Singer et al in view of Curatolo et al, appellant contends that the declaration of Richard Todd Darrington should have been considered for the purpose of removing Singer as a reference against claims 125 and 128-144 because it showed the date of the invention of the subject matter of claims 125 and 128-144 was before May 8, 1998 or before the earliest priority date of Singer.

This argument has not been found persuasive because a declaration under 37 CFR 1.131 is not sufficient where the reference is a domestic patent which is claiming a substantially the same invention as the appellant. In the instant case, the claims of Singer et al are directed to azithromycin ethanolate. A dosage form of azithromycin ethanolate in combination with a carrier is substantially the same invention as azithromycin ethanolate.

Appellant also contends that Singer does not teach dosage form of substantially pure azithromycin monohydrate hemi-ethanol solvate in a pharmaceutical dosage form having NMR spectrum as encompassed by the present claims. This argument has not been found persuasive claim 1 of the Singer et al patent reads on azithromycin ethanolate having ethanol content of about 3% which encompasses substantially pure azithromycin ethanolate. Appellant has not presented any evidence showing that the compound

encompassed by the present claims is different from the compound disclosed by Singer et al.

Appellant contends that one of ordinary skill in the art would not know from Singer and Curatolo how to obtain the claimed pharmaceutical dosage form. This argument has not been found persuasive. On page 32 of the specification, lines 25-36, it is stated the "active compound may be administered in a wide variety of different dosage forms, i.e. they may be combined with various pharmaceutically acceptable inert carriers in the form of tablets...". Note that Singer et al disclose composition comprising azithromycin ethanolate in combination with pharmaceutically acceptable carriers and in the form of a tablet (column 3, lines 15-25).

Appellant also argues that Rouhi article should be considered as suggesting an expectation that drug crystals would convert to other crystal forms in dosage forms. This argument has not been found persuasive. Appellant has successfully argued in reply filed January 17, 2006 that Rouhi reference does not suggest that the claimed azithromycin monohydrate hemi-ethanolate can convert to a different polymorph.

Appellant further contends that a pharmaceutical dosage form containing substantially pure azithromycin monohydrate hemi-ethanol solvate is unexpected. This argument has not been found persuasive since no verified evidence of unexpected results has been presented for consideration.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Elli Peselev

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